8. 510(k) Summary:

Contact person:	Dick Roberts, Division President 541-A Birch St. Lake Elsinore, CA 92530 (909) 245-3656 Fax: (909) 245-3656
Date Prepared:	March 12, 2001
Device Information:	
Trade Name:	Bioconnect Patient Cable and Leadwire system.
Common Name:	Patient Cable and Leadwires.
Classification Name:	Cable, Transducer and Electrode, Patient, (Including Connector).
Device Classification:	Class II Cardiovascular, DSA, (CFR: part 870.2900)
Predicate Devices:	These devices are Substantially Equivalent to legally marketed devices manufactured by: Tronomed, Inc., 510(k) K952659 and K771645 Merit Industries, 510(k) K942321
Device Description:	The Bioconnect Cable and Leadwire system connects a variety of Physiological Monitoring Devices to disposable sensing elements attached to the patient. The system is made up three (3) basic elements, a trunk cable, patient leadwires, and instrument connector. The design and wiring configuration of the instrument connector varies according to the individual specifications of the Instrument Manufacturer.
Intended Use:	The only intended use for the Cable and Leadwire system is to conduct physiological signals between sensors attached to the body and the Physiological Monitoring Device in use.
Performance Standard:	All criteria of ANSI/AAMI EC53 – 1995 are met.
Comparison Table to Predicate Device:	Comparison table found on next page.

541-A Birch St. – Lake Elsinore, CA 92530 – (909) 245-3656 Fax: (909) 245-3656
Email: binfo@bioconnectinc.com - www.bioconnectinc.com

Bioconnect Product Comparison Table to Predicate Devices

	Bioconnect	Tronomed	Merit
Only intended use	Conduct physiological signals between body sensors and physiological monitoring and diagnostic devices.	Same	Same
Patient usage	Reusable	Same	Same
Anatomical Sites	Attached to sensors placed at specific locations on the body.	Same	Same
Design and Appearance	A length of cable or wire with the appropriate connector or contact attached and over molded on each end.	Same	Same
Design of instrument interface connector	Various, to comply with Instrument Manufacturer Specifications.	Same	Same
Design of Patient yoke and Leadwire interface.	Complies with ANSI/AAMI EC53—95 and Trunk Cable/Patient Leadwire interconnection requirements of DIN 42-802	Same	Same
Sterility	Used non-sterile	Same	Same
Electrical Performance	Meets or exceeds ANSI/AAMI EC53 American National Standard	Same	Same
Electrical Safety	Meets or exceeds ANSI/AAMI EC53 American National Standard as well as DIN 42-802 standard for Safety/Touch Proof patient connecting leads.	Same	Same
Materials used	Copper conductors for wire and cable. Brass, nickel and gold contacts. Wire/Cable insulation and molding materials are various Thermo Plastic Elastomers including, PVC, TPR, Urethane, and others.	Same	Same

Conclusion: This comparison chart demonstrates a substantial equivalence to predicate devices manufactured by:

Predicate Manufacturer	Predicate Device	510(k) Number
Tronomed, Inc.	Patient Cable and Leadwire Systems	K952659 and K771645
Merit Industries	Various Patient Monitoring Cables	K942321

This 510(k) summary of safety and effectiveness information of product is submitted in accordance with the requirement of 21 DFR 807.92(c)

541-A Birch St. – Lake Elsinore, CA 92530 – (909) 245-3656 Fax: (909) 245-3656
Email: binfo@bioconnectinc.com - www.bioconnectinc.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Mr. Dick Roberts
RF Industries, Ltd.
Bioconnect
541-A Birch Street
Lake Elsinore, CA 92530

Re: K010809
Trade Name: Bioconnect Patient Monitoring Cables and Leadwires
Regulation Number: 870.2900
Regulatory Class: II (two)
Product Code: DSA
Dated: March 12, 2001
Received: March 16, 2001

Dear Mr. Roberts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

2. Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: Bioconnect, Division of RF Industries

510(k) Number (if known): Unkown

Device Name: _Bioconnect: Patient Cable and Leadwire Systems

Indications For Use:

Bioconnect's Patient Cable and Leadwire System is only for use as an interface between various Diagnostic and Physiological Monitoring Devices (Not manufactured by Bioconnect) and disposable sensor devices (Not manufactured by Bioconnect) which are attached to a patients body. Bioconnect, Patient Cable and Leadwire Systems are limited by the Indications for Use of the connected Diagnostic or Physiological Monitoring Device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010897

X Prescription Use